

### **STATUS OF CLAIMS**

Claims 1-104 are pending in the application. Claims 1-72 were withdrawn pursuant to an election requirement. Applicant hereby amends independent claims 73 and 87. Support for the amendments to claims 73 and 87 are found in the original application as filed and specifically, in paragraphs [0065] and [0066] of the specification and the drawings referenced therein. Applicant has amended claims 96, 98, and 99 in accordance with the Examiner's suggestion. Applicant states that there is no issue of new matter.

### **REMARKS**

Applicant acknowledges that the Examiner has withdrawn the double patenting rejection of claims 73-74, 76-7, 80-82, 84, and 86.

Applicant also acknowledges that the Examiner has withdrawn the rejection of claims 73-74, 76-77, and 84 as anticipated by Pinchuk et al and withdrawn the rejection of claims 75, 78-83 and 85-94 as being obvious over Pinchuk et al.

Applicant also acknowledges that the Examiner has withdrawn the rejection of claims 73-94 as anticipated by Pinchuk et al.

Applicant also acknowledges that the Examiner has withdrawn the rejection of claims 73-74, 76-77 and 84 as anticipated by Bucay-Couto et al.

The Examiner states that Applicant's arguments did not address the rejection of claims 80, 81 and 86 as obvious over Bucay-Couto et al. and thus maintains his rejection of those claims over Bucay-Couto et al.

In addition, the Examiner provided the new grounds of rejection as follows.

#### **Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 96, 98, and 99 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner states that the Applicant is claiming alternatives but not presented in Markush format. For example, the Examiner states that claim 98 recites a broad recitation as well as a narrower statement of the range/limitation.

In response, Applicant respectfully traverses the rejection. However, in order to expedite the prosecution of the application, Applicant has amended claims 96, 98, and 99 to place them into Markush format, obviating the rejection.

**Rejection Under 35 U.S.C. § 102(a)/(e) – Modak et al.**

Claims 75, 80, 89, 95-97 and 103 are rejected under 35 U.S.C. § 102(a)/(e) as being anticipated by Modak et al. (U.S. Pat. No. 6,224,579).

In response, Applicants respectfully traverse the rejections and their accompanying remarks. Modak et al. does not teach the invention of the claims. Specifically, Modak et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 73, which is directed to

a stent comprising a polymeric tubular shaft *having more than one layer*, said polymeric tubular shaft comprising a first annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, *a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.* (emphasis added).

Modak et al. also fails to teach all of the elements of the present invention as claimed in amended independent claim 87, which is directed to

a ureteral stent comprising a polymeric tubular shaft that is between 0.2 mm and 0.8 mm in wall thickness, said polymeric tubular shaft *having more than one layer* and comprising a first annular layer comprising (a) polymeric species consisting essentially of ethylene vinyl acetate copolymer and (b) antimicrobial species consisting essentially of triclosan;  
*a first polymeric barrier layer at least partially covering an interior surface of said first annular layer;*  
*and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.* (emphasis added).

The Modak et al. reference fails as an anticipatory reference because it fails to disclose *all* of the features of the claimed invention. Specifically, Modak et al. fails to teach a polymeric tubular shaft that is made of *more than one layer*. It does not teach either a first or a second barrier layer that at least partially covers an exterior and interior surface, respectively of a first annular layer. Indeed, the words “barrier” or “barrier layer” do not appear anywhere in Modak et

al. The word “layer” does not appear anywhere in Modak et al. Modak et al. simply does not disclose a device having a polymeric tubular shaft made of more than one layer. Instead of layers, Modak et al. teaches “direct impregnation of triclosan and a silver compound into a Dacron device” by dipping the device into a “treatment solution...prepared including 1 to 6 percent triclosan and 0,1 to 0.2 percent of a silver compound in a solvent mixture...The device may be soaked for 1 to 10 minutes, dried and rinsed.” (Modak et al., col. 10, lines 1-20).

In addition to failing to teach **all** of the claimed **elements**, the reference still fails because Modak et al. does not teach the claimed stent **structure**. As claimed, the invention is directed to an annular layer in the middle, with outer barrier layers such that at least a part of the interior surface of the annular layer is covered with a first barrier layer and at least a part of the exterior surface of the annular layer is covered with a second barrier layer. Modak et al. simply does not teach any such multi-layer structure.

For a reference to anticipate a claim it must disclose **each and every element** of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added). Modak et al. simply does not.

**Rejection Under 35 U.S.C. § 102(e)/103(a) – Modak et al.**

Claims 84 and 90 are rejected under 35 U.S.C. § 102(a)/(e) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Modak et al.

Claims 81-88 and 94 are rejected under 35 U.S.C. § 103(a) as being obvious over Modak et al.

Claims 76-79 and 91-93 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Modak et al. in view of Schwartz et al. (U.S. Pub. No. 2001/0022988).

Claims 100-101 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Modak et al. in view of Buscemi et al (U.S. Pat. No. 5,693,034).

Claims 102 and 104 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Modak et al in view of Schwarz et al. and further in view of Falk et al.

In response, Applicants respectfully traverse the rejection and their accompanying remarks.

Regarding the 102(c) rejection of claims 84 and 90, given the arguments above and amendments to independent claims 73 and 87, upon which the rejected claims depend, respectively, claims 84 and 90 are not anticipated by Modak et al. Modak et al. fails to teach all of the elements of the rejected base claims by failing to teach a polymeric tubular shaft that is made of *more than one layer*. It also fails to teach either a first or a second barrier layer that at least partially covers an exterior and interior surface, respectively of a first annular layer, as required by base claims 73 and 87.

Regarding the obviousness rejection of claims 84, 90, 81-88, and 94 over Modak et al., Applicant respectively traverses the rejection and its accompanying remarks. The Examiner asserts that the obviousness of the various of the additional dimensional and material features provided in these claims are “now admitted prior art.” Applicant states that such assertion is *erroneous*. Applicant has previously asserted and also presently asserts that all of the rejected claims are not obvious over the cited art. Regarding claims 81-88 and 94, Applicant states that the previous rejection of these claims was traversed by the Applicant and such rejection was *withdrawn by the Examiner*. Further, all of Applicant’s arguments with respect to the base independent claims upon which these claims depend, apply to these claims as well. In addition, these claims contain additional distinguishing features. Applicant states that no admission as to obviousness was made either explicitly or implicitly and requests that the Examiner provide legal authority to support such assumption.

Regarding the new ground for rejection of claims 81-88, and 94 as unpatentable over Modak et al., Applicant respectfully traverses the new rejection of the claims as obvious in light of Modak et al.

Applicant states that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants state that the rejection fails at least because of the fundamental defects discussed above regarding the rejection under 35 U.S.C. § 102(e) over Modak et al. As indicated above with respect to the anticipatory rejection over Modak et al., Modak et al. fails to teach all of the claimed features of the independent claims and also the dependent claims which contain additional distinguishing features.

**Rejection Under 35 U.S.C. § 103(a) – Modak et al. in view of Schwarz et al.**

Claims 76-79 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. in view of Schwarz et al. (US 2001/0022988). The Examiner asserts that Modak et al. discloses a stent as discussed above, except that Modak et al. does not disclose use of ethylene vinyl acetate copolymer.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Modak et al. in combination with Schwarz et al. fail to teach or suggest the invention of the claims, as amended. Applicant reiterates all of the arguments evidencing the deficiencies of Modak et al. provided above. In addition to those deficiencies noted by the Applicant, the Examiner admits that “Modak et al. does not disclose use of ethylene vinyl acetate copolymer.”

To remedy the deficiency in Modak et al., the Examiner turns to Schwarz et al. for purportedly teaching another stent that uses ethylene vinyl acetate copolymer for the purpose of holding drugs for local delivery. Unfortunately, the combination of Modak et al. and Schwarz et al. must fail. Even if it were assumed for the sake of argument that Schwarz et al. teaches ethylene vinyl acetate copolymers, Schwarz et al. does not remedy the other many deficiencies of Modak et al. and the combination of the two fail to teach each and every element of the claimed invention, which is required to establish a *prima facie* case of obviousness. Swartz et al. reference fails to teach a polymeric tubular shaft that is made of more than one layer or a first or a second barrier layer that at least partially covers an exterior and interior surface, respectively of a first annular layer.

For at least these reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e)/103(a) over Modak et al. in view of Schwarz et al. be withdrawn.

### CONCLUSION

Given the above remarks and amendments to the claims, Applicants state that the Examiner's rejections under 35 U.S.C § 102(a)/(e) and § 103(a) have been obviated and Applicants respectfully requests that the Examiner withdraw the rejections. Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

### FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

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Respectfully submitted,

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